

within the new journal can be divined. There is no reference to the second hand methodology, just the quoting of subjectively attractive and unqualified conclusions, fourth hand.

Those who are concerned with validity will examine raw data and access much more extensive databases by standard methods on the Internet on a more comprehensive scale at only second hand level. Those who are not concerned with validity will find a ready substitute for thought and effort. At best, evidence based medicine is a heuristic method for a lower level partial abstracting service. There is little new or of merit in this allegedly new discipline. Assessing the raw data and understanding their validity and the means of their creation make up the true evidence based foundation of scientific and academic inquiry.

Evidence based medicine in its present form is inconsistent and incompatible with science, and its lack of soundness is sufficient for us to consider whether it is even ethical. Neither the Renaissance nor the Reformation, during which the direct examination of the human body by Vesalius and Leonardo da Vinci replaced the evidence based teachings of Galen, would have been possible without the abandonment of contemporary evidence based systems. To a scientist, the advent of evidence based medicine creates an unassailable gulf and denies the fundamental tenets of millenniums of thought and philosophy of inquiry. To a university teacher devoted to honest original inquiry, it is a falsehood. And we are going to teach it, as an allegedly new specialty, in the new medical school curriculum recommended by the General Medical Council's medical education subcommittee.

NIGEL T JAMES  
Senior lecturer

Department of Biomedical Science,  
University of Sheffield,  
PO Box 601,  
Sheffield S10 2TN

- 1 Sackett DL, Rosenberg WMC, Muir Gray JA, Haynes RB, Richardson WS. Evidence based medicine: what it is and what it isn't. *BMJ* 1996;312:71-2. (13 January.)

## Authors' redefinition is better but not perfect

EDITOR,—Although David L Sackett and colleagues have attempted to redefine evidence based medicine, they still argue that not everyone can be using it as striking variations in the uptake of treatments remain.<sup>1</sup> This look at outcome data raises a further question about outcomes: are cohort mortalities strikingly different in the various regions where uptake is different? We are given data to say whether people are using evidence based medicine but not whether treatment, according to the new principles, is working. Is the best evidence to be found in an evidence based database, or for certain questions can we be sure that such databases will be useless and we should look elsewhere?

We think it unlikely that papers that report harm will get into evidence based databases. In the same issue of the *BMJ* as Sackett and colleagues' editorial, Teifion Davies, in a commentary on a paper, states that "the clearest evidence of a causal relation [between antipsychotic drugs and sudden death] comes from a series of case reports."<sup>2</sup> As that evidence is a series of case reports<sup>3</sup> one will look for it in an evidence based database in vain. It will have been excluded because one of the prime criteria for inclusion, a control group for comparison, is lacking.

Sackett and colleagues say that criticism of evidence based medicine ranges from it "being old hat to it being a dangerous innovation," but they do not say that a criticism is also that the databases may not contain the information we want, or perhaps need, to avoid litigation. For

example, if anaesthetists wish to have information on side effects of new drugs they may, if they access a database, be misled into thinking that no evidence exists when it does exist but has been excluded. Even old evidence on old drugs may not be there: McBride's original observations on thalidomide did not have a control group.<sup>4</sup> Case series of side effects of suxamethonium<sup>5</sup> or propofol would, because of a lack of controls, not feature in databases of best practice; nevertheless, it would be difficult to say that anaesthetists' practice is better because they do not know of them.

Sackett and colleagues' efforts to redefine evidence based medicine can be summed up as "better but not perfect."

OLIVER R DEARLOVE  
Consultant paediatric anaesthetist  
JO ROGERS  
Registrar  
ANDREW SHARPLES  
Consultant paediatric anaesthetist

Royal Manchester Children's Hospital,  
Pendlebury,  
Manchester M27 1HA

- 1 Sackett DL, Rosenberg WMC, Muir Gray JA, Haynes RB, Richardson WS. Evidence based medicine: what it is and what it isn't. *BMJ* 1996;312:71-2. (13 January.)
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- 4 McBride WG. Thalidomide and congenital abnormalities. *Lancet* 1961;iii:1358.
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## Needs to be within framework of decision making based on decision analysis

EDITOR,—What evidence is there that clinicians' skill includes knowledge of how, explicitly, to integrate the best external evidence into an optimal decision for the patient in front of them?<sup>1</sup> A reasonable answer would be "none." Is the process involved in evidence based medicine, as reported, capable of ensuring that decision owners (patients) know how, explicitly, their preferences are to be integrated into decisions affecting them? A reasonable answer would be "no."

These two answers lead to the conclusion that the many undoubted virtues of evidence based medicine will bear fruit for most patients only when they occur within the overarching framework provided by medical decision making based on decision analysis.<sup>2</sup> Unless this happens, evidence based medicine is likely to prove an expensive way of changing the process and appearance of medical practice without improving the quality of outcomes for patients, properly evaluated.

JACK DOWIE  
Senior lecturer

Faculty of Social Sciences,  
Open University,  
Milton Keynes MK7 6AA

- 1 Sackett DL, Rosenberg WMC, Muir Gray JA, Haynes RB, Richardson WS. Evidence based medicine: what it is and what it isn't. *BMJ* 1996;312:71-2. (13 January.)
- 2 Dowie J. "Evidence based," "cost-effective" and "preference-driven" medicine: decision analysis based medical decision making is the pre-requisite. *Journal of Health Services Research and Policy* (in press).

## Cost effectiveness and equity are ignored

EDITOR,—David L Sackett and colleagues' editorial on evidence based medicine is confused and inadequate.<sup>1</sup> The authors argue, among other things, that "doctors practising evidence based medicine will identify and apply the most

efficacious interventions to maximise the quality and quantity of life for individual patients." (Note the use of "apply" (does the patient have no choice?) and "efficacious" rather than effective.)

This individual medical ethic has to be traded off against the social ethic of the efficient use of scarce resources. While the individual patient might welcome treatment regardless of cost, any health care system is unlikely to be able to afford or condone such behaviour. Society requires doctors to allocate resources on the basis of knowledge of cost effectiveness. This obliges doctors to deny patients access to efficacious treatments if such interventions are not cost effective. Failure to do this without reasonable cause means that scarce resources are wasted and patients who could benefit from care are left untreated. Such inefficient treatment is unethical and should be construed by employers as prima facie evidence for dismissal in an NHS striving to maximise health benefits from its £40 bn budget.

The necessity to ration or allocate care on the basis of cost effectiveness was recognised by Archie Cochrane nearly 25 years ago: "Allocations of funds and facilities are nearly always based on the opinions of senior consultants, but, more and more, requests for additional facilities will have to be based on detailed arguments with 'hard evidence' as to the gain to be expected from the patient's angle and the cost. Few can possibly object to this."<sup>2</sup>

Nowadays we would complement Cochrane's position by noting that the goal of efficiency might be mediated by considerations of equity—that is, society might deliberately decide to forgo efficiency (health gains) to discriminate in favour of poor people. It is remarkable that the approach of evidence based medicine ignores such considerations and, in so doing, favours the middle class, which has a greater capacity to benefit from care, rather than poor people, who, if treated, will yield fewer health gains because of their "mean" condition.

It is a pity that the so called apostles of Cochrane have yet to understand his gospel of cost effectiveness and be concerned by considerations of equity, which would have been close to his heart.

ALAN MAYNARD  
Secretary

Nuffield Provincial Hospitals Trust,  
London W1M 7RD

- 1 Sackett DL, Rosenberg WMC, Muir Gray JA, Haynes RB, Richardson WS. Evidence based medicine: what it is and what it isn't. *BMJ* 1996;312:71-2. (13 January.)
- 2 Cochrane AL. *Effectiveness and efficiency: random reflection on health services*. London: Nuffield Provincial Hospitals Trust, 1972.

## Authors' reply

EDITOR,—Blair H Smith and Nigel T James have not done their homework. The crucial importance of clinical skill and the roles of both patients' needs and non-randomised evidence were emphasised four years ago in our initial paper on evidence based medicine.<sup>1</sup> Methodological and clinical criteria for articles in *Evidence-Based Medicine* are published in every issue, as is a glossary explaining methods and terms. Commentaries are signed, and both the commentators and authors of the original articles collaborate in writing the abstracts.

We agree with Oliver R Dearlove and colleagues about the challenges that clinicians face in searching for the best external evidence. When secondary sources of best evidence are silent we must extend our search into the primary literature.

Jack Dowie maintains that only decision analysis can provide the framework necessary for making evidence based medicine (and economic analysis) work. As we have described in texts<sup>2</sup>

and workshops, this might be so in an ideal world. But today's harsh realities (the paucity of reliable methods and the inability of busy clinicians to find the 12 hours that a typical clinical decision analysis consumes) render it impossible for us to perform this for more than a handful of our patients.

Alan Maynard continues to flay clinicians who acknowledge and confront the simple fact that our responsibilities to individual patients (when maximising their quality of life is the goal) will sometimes conflict with our responsibilities to society (when optimising cost utility is the goal).<sup>3</sup> We attempt to minimise these conflicts by rejecting costly but ineffective procedures and by continuing our search for more cost effective ways of caring for our patients (for example, an entire section of *Evidence-Based Medicine* is dedicated to economic analyses). Other health economists recognise that an evidence based approach will help minimise this conflict and are collaborating with health workers to establish the complementary discipline of evidence based purchasing and management. Maynard ignores these efforts and simply calls for us to be sacked if we do not obey his diktats. Moreover, his ignorance of what happens in clinical medicine remains intact ("efficacious" accurately describes the evidence to be integrated with patients' values and expectations as we collaborate with the patients in deciding whether, and if so how, the evidence would be "applied" to their predicaments). Maynard has a standing invitation (already taken up by other economists who wanted to learn about front line health care<sup>4</sup>) to join our clinical team.

DAVID L SACKETT

Professor in medicine

WILLIAM M C ROSENBERG

Clinical tutor in medicine

Nuffield Department of Clinical Medicine,  
University of Oxford,  
Oxford OX3 9DU

J A MUIR GRAY

Director of research and development

Anglia and Oxford Regional Health Authority,  
Milton Keynes MK14 6QP

R BRIAN HAYNES

Professor of medicine

McMaster University,  
Hamilton,  
Ontario,  
Canada L8N 3Z5

W SCOTT RICHARDSON

Associate professor of medicine

University of Rochester,  
Rochester, NY,  
USA 14621

1 Evidence-Based Medicine Working Group. Evidence-based medicine. *JAMA* 1992;268:2420-5.

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## Bovine spongiform encephalopathy

### Disease is due to pressure on farming industry

EDITOR,—I agree with A J McMichael's statement that bovine spongiform encephalopathy may in some way be due to the build up of pressure on the farming industry.<sup>1</sup> As a researcher into the disease I have had to investigate the reasons why it has occurred in Britain and apparently not elsewhere. It became clear to me that the economics of the highly efficient system in Britain were involved.

Farmers in Britain are commonly tenants, and so their rent can increase when profits increase (for example, due to the common agricultural policy).

As a result, no matter what the potential profitability of a method being used is, there is continuous high pressure on the system to become more efficient. This led to the use of the most productive cattle for lactation; the most effective pesticides for the price; the most effective rendering plants; and any good, reasonably priced source of protein in the bovine diet. The result was that over 95% of the dairy cattle in Britain were from three breeds and the vast majority were Holstein-Friesian, and the renderers were almost all owned by two companies and used a single method for producing feed. Profits were relatively low but reliable, as long as the European Union kept the prices up and the Ministry of Agriculture, Fisheries and Food supplied technical help and help with sales.

The problem with this is that if one thing goes wrong then the mistake or risk applies to the whole system, which collapses; the individual companies and farmers have little to fall back on. As a result, the Ministry of Agriculture, Fisheries and Food believes that it must back up the farmers and bring back confidence, even when this confidence is not justified (eggs really were contaminated with *Salmonella* and pâté with *Listeria*, and bovine spongiform encephalopathy infected large numbers of cattle being eaten and could not be assumed to be a low risk).

The emergence of bovine spongiform encephalopathy shows how pressure towards high efficiency leads to nationally organised, relatively fragile, single method systems that can collapse easily and may depend on the suppression or denial of information in the short term for such collapse to be avoided. What happens when a disease such as bovine spongiform encephalopathy appears that is potentially fatal to a considerable proportion of the population<sup>2</sup> but proof for or against this will not become available for several years? Under the current system either attempts are made to assure the consumers of the safety of the food (with inadequate justification) or the industry collapses. As McMichael states, it is the pressure on the system that leads to this, and it will happen repeatedly as the pressure increases.

STEPHEN DEALLER

Consultant microbiologist

Burnley General Hospital,  
Burnley BB10 2PQ

1 McMichael AJ. Bovine spongiform encephalopathy: its wider meaning for population health. *BMJ* 1996;312:1313-4. (25 May.)

2 Pattison J. *Agriculture and Health Select Committee 1995-1996*. London: HMSO, 1996:79. (HC-331.)

### Media coverage had shortlived effect on beef consumption by pregnant women

EDITOR,—K D Gunasekera and colleagues comment on the public recognition of scientific uncertainty about the risk of developing Creutzfeldt-Jakob disease after eating beef.<sup>1</sup> Their conclusion is supported by our data, which indicate that although almost three quarters of women stopped eating beef in the week after the media coverage of the scare, this reaction was short lived.

A study collecting information about folic acid supplementation by pregnant women is also collecting dietary information,<sup>2</sup> asking about food eaten in the past week; information is collected about 20 common foods containing varying levels of folates. During the 10 weeks 29 January to 21 April 1996, 409 pregnant women attending three hospitals in Birmingham were recruited to the study. All were attending a maternity hospital booking clinic; 294 were in the first trimester of pregnancy. The ages of the respondents ranged from 15 to 46 (mean 27.9 years). The catchment areas of the participating hospitals have varied socioeconomic and ethnic compositions.

Four hundred women (98%) completed the dietary section of the questionnaire; 105 reported

**Table 1—Number (percentage) of respondents who reported having eaten beef in past week**

Period	No recruited	Had eaten beef	
		No	Yes
29 Jan to 17 Mar	163	104 (64)	59 (36)
Week beginning:			
18 Mar	36	26 (72)	10 (28)
25 Mar	20	18 (90)	2 (10)
1 Apr	89	73 (82)	16 (18)
8 Apr	27	24 (89)	3 (11)
15 Apr	65	50 (77)	15 (23)
Total	400	295 (74)	105 (26)

that they had eaten beef during the previous week. The media coverage of the 10 cases of Creutzfeldt-Jakob disease in young people occurred in the week beginning 18 March.<sup>3</sup> In the five weeks preceding this announcement 59 (36%) of the 163 women recruited reported that they had eaten beef at least once during the previous week (table 1). In the four weeks after the media coverage the proportion of women reporting having eaten beef fell to 36 (18%) of 201 women ( $\chi^2 = 15.6$ ,  $P = 0.00008$ ). Asians reported eating beef less frequently than other ethnic groups (4/44 (9%) v 101/356 (28%);  $\chi^2 = 7.52$ ,  $P = 0.006$ ). However, adjustment for weekly variation in the proportion of vegetarians (24 (6.0% of the study population)) and Asians (44 (10.8%)) recruited does not explain the observed fluctuation in consumption of beef.

Data for the most recent week (beginning 15 April) show that the rate of beef consumption had risen to 23%, which suggests that it was reverting towards former levels. Possibly, pregnant women are more health aware than the general population. These data suggest, however, that the dramatic fall in beef consumption after the heavy media coverage was short lived. This could mean either that the public has identified the scientific uncertainty or that after an initial reaction most of the public rapidly reverts to usual behaviour patterns. If the latter hypothesis is correct this may have implications for government health warnings and health education policy.

SUE WILSON

Research fellow

SANDY MCLEOD

Research associate

ANNE GILLIES

Clinical research fellow

Department of General Practice,  
Medical School,  
University of Birmingham,  
Birmingham B15 2TT

YVONNE CARTER

Professor

Department of General Practice and Primary Care,  
St Bartholomew's and Royal London School of Medicine and  
Dentistry,  
London EC1M 6BQ

1 Gunasekera KD, Hapgood AI, Harvey EL, Hayfron Benjamin TRM, Jachuck MSJ, Jackson ALN, et al. Creutzfeldt-Jakob disease and bovine spongiform encephalopathy. *BMJ* 1996;312:1038. (20 April.)

2 Gillies A, McLeod S, Carter Y. Periconceptual folate supplementation. *Br J Gen Pract* 1996;46:254.

3 Brown D. Farmers fear backlash from consumers. *Daily Telegraph* 1996 Mar 21:1.

### Doctors are less likely than patients to have stopped eating beef

EDITOR,—There has been saturation coverage in the media and several articles in medical journals about the possible relation between bovine spongiform encephalopathy, Creutzfeldt-Jakob disease, and consumption of British beef.<sup>1-4</sup> The speculation and hype surrounding this latest food scare have resulted in confusion about the true risks of eating beef. I conducted a study of